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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,947	05/15/2002	Atef Gayed	MAR618/4-5(A)US	8100
7590	05/04/2005			
Timothy S Corder Vinson & Elkins 2300 First City Tower 1001 Fannin Street Houston, TX 77002-6760				
			EXAMINER SCHNIZER, HOLLY G	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 10/031,947	Applicant(s) GAYED, ATEF	
	Examiner Holly Schnizer	Art Unit 1653	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-72.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

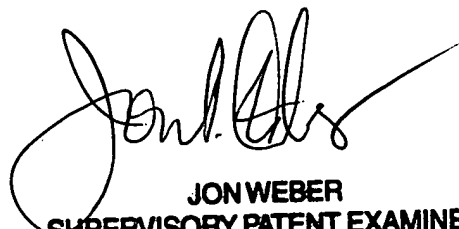
#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 4/1/05  
13. ☐ Other: \_\_\_\_\_.

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Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection of claims 4-15 and 23-33 under 35 U.S.C. 12, second paragraph.

Continuation of 11. does NOT place the application in condition for allowance because: the rejection of claims 20, 23-27, and 34 under 35 U.S.C. 102(b) has not been overcome by the amendment because the claims still do not require the presence of erythropoietin in the composition but only require that the claimed composition have an intended use as a carrier of erythropoietin. Thus, the claims remain rejected for reasons cited in the previous Office Actions. The rejection of Claim 1 as anticipated by Nomura et al. is maintained for reasons cited in the previous Office Actions. Applicants arguments that it was not obvious to add benzethonium chloride to EPO compositions and that Nomura et al. fails to suggest the compositions of the present invention are not persuasive because the issue at hand is one of anticipation not of obviousness. Applicants have not presented any evidence that the concentrations of benzethonium chloride present in the Nomura et al. composition would not be effective to inhibit microbial growth. Thus, for reasons stated in the previous Office Actions, the compositions of Nomura et al. appear to be patentably indistinguishable from that of claim 1. The rejection of Claims 1, 4, 5, 7, 8, 16-20, 23, 24, 26, 27, 34-35, 50-54, 57-61, and 69-72 under 35 U.S.C. 103(a) as obvious over Strickland et al. in view of Uda et al. and Sandeep et al. is maintained for reasons cited in previous Office Actions. Applicants argue that Strickland teach away from the present invention. However, the statement cited by Applicants refers to the knowledge in the art before Strickland. The Strickland patent shows that antimicrobials related to benzethonium chloride may be used to stabilize EPO compositions for up to 2 years (Col. 4, lines 57-60). Strickland states that preservatives useful are those that are compatible with EPO. This suggestion in view of Uda et al., showing that that benzethonium chloride and benzalkonium chloride are functional equivalents (both in the same class of preservatives; see Col. 6, lines 28-35)) and suggesting that benzethonium chloride is compatible with EPO (Col. 3, line 63; also see p. 5 of Office action mailed 5/26/04); and Sandeep et al., indicating that benzethonium chloride and benzalkonium chloride were routinely used as antimicrobial preservatives (functional equivalents), renders the present claims obvious. Applicant's arguments concerning the rejection of Claims 2, 3, 6, 9-15, 21-22, 25, 28-33, 36-49, 55-56, and 62-68 as obvious in view of Strickland et al., Uda et al, and Sandeep et al. and further in view of Hyman et al. are not persuasive for the reasons cited in the previous Office Actions. In response to applicants argument based upon the age of the references, contentions that the reference publications are old are not impressive absent a showing that the art tried and failed to show a synergistic effect upon adding an additional antimicrobial to a composition containing benzethonium chloride. The rejection of Claims 1, 4-8, 16-19, 35, 38-42, and 50-53 as obvious over Kakimoto et al., Shimodo et al., and Uda et al. is maintained for reasons cited in previous Office actions. In response to Applicants arguments against the references individually, one cannot show nonobviousness by attacking the references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).



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